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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,020	11/08/2000	Christoph Benning	MSU-04769	3130

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	17

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/709,020	BENNING ET AL.	
	Examiner	Art Unit	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13 and 15-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,13 and 15-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed October 29, 2002, amending claims 1, 13, 15 and 16 and adding claims 17-34, has been entered.

Claims 1, 13, 15, 16 and 17-34 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps in isolating the final product is missing.

Claim Rejections - 35 USC § 103

Claims 17-25 are rejected under 35 U.S.C. 103(a) as being obvious over Benning in view of Essigmann et al. and Guler et al. in further view of Stratagene Catalog, Hall et al. and Howard et al.

Benning (form PTO-1449) teach SQDG biosynthesis is a two-step reaction starting with UDP-glucose as the precursor to UDP-SQ (UDP-sulfoquinovose), which is the precursor to SQDG (page 61, 2nd paragraph). In addition, Benning teaches a

pathway for the production of UDP-SQ from UDP-glucose with SQDB protein and a pathway for the production of SQDG from UDP-glucose with sqdX as the enzyme that converts UDP-SQ into SQDG (figure 3, page 62). Benning teaches that sqdX from Synechococcus sp. Catalyzes the reaction of UDP-SQ into SQDG. SqdX is inherently identical to SEQ ID NO:1 of the instant invention, as evidenced by Guler et al. (page 545, 1st paragraph).

Benning also teach that sulfite can be used as the sulfur donor (page 66, 2nd paragraph). Benning et al. also teach that SQDG of photosynthetic bacteria and plants are a promising anti-tumor and anti-HIV therapeutic (page 54, 1st paragraph).

The difference between the reference of Benning and the instant invention is that the reference of Benning does not teach a method of producing UDP-SQ from UDP-glucose with the polypeptide encoded by SEQ ID NO:6.

Essigmann et al. teach a polypeptide, plant SQD1, that catalyzes the formation of a UDP-sulfoquinovose from UDP-glucose and is orthologous to the SQDB (page 31, 4th paragraph and page 39). The SQD1 gene is 100% identical to SEQ ID NO:6 of the instant invention (GenEmbl database – Accession # AF022082). Essigmann et al. teach that said SQD1 gene and the bacterial sqdB gene (as mentioned above) are the only sufolipid genes known to be conserved between different organisms (page 31, 5th paragraph).

Essigmann et al. teach a method for transfecting a host cell with a DNA to express the encoded enzyme (page 32, 5th paragraph). Although Essigmann et al.

states that the sulfur donor is unknown, Essigmann et al. teaches that a sulfite is a plausible sulfur donor (page 40, 3rd paragraph).

Transfecting a host cell with a desired gene is well known and practiced in the art (see Hall et al. – background) and multiple or sequential transformation is well known and practiced in the art. Many catalogs carry vectors and host cells capable of undergoing multiple transformations (pages 34-84 and appendix). Hall et al. teach host cells derived from dicotyledonous plants (see claims and Column 11) and Howard et al. teach host cells derived from monocotyledonous plants (Column 6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute the first reaction of SQDG synthesis of Benning with the SQD1 enzyme of Essigmann et al. The motivation of using the SQD1 is to provide a system in synthesizing SQDG using genes from a plant source and a bacterial source, thereby possibly increasing efficiency in production of SQDG. An efficient production of SQDG is attractive because sulfolipids are possible anti-tumor and anti-HIV therapeutics. One of ordinary skill in the art would have had a reasonable expectation of success since Benning outlines the pathway for SQDG production and production of a product using heterologous or orthologous enzymes are routinely performed in the art.

Claims 26-34 are rejected under 35 U.S.C. 103(a) as being obvious over Benning in view of Essigmann et al. and Bevan et al. in further view of Stratagene Catalog, Hall et al. and Howard et al.

Benning (form PTO-1449) teach SQDG biosynthesis is a two-step reaction starting with UDP-glucose as the precursor to UDP-SQ (UDP-sulfoquinovose), which is the precursor to SQDG (page 61, 2nd paragraph). In addition, Benning teaches a pathway for the production of UDP-SQ from UDP-glucose with SQDB protein and a pathway for the production of SQDG from UDP-glucose with sqdX as the enzyme that converts UDP-SQ into SQDG (figure 3, page 62). Benning teaches that sqdX from Synechococcus sp. Catalyzes the reaction of UDP-SQ into SQDG.

Bevan et al. (from PTO-892) teach a sqdX gene which is 100% identical to SEQ ID NO: 3.

Benning also teach that sulfite can be used as the sulfur donor (page 66, 2nd paragraph). Benning et al. also teach that SQDG of photosynthetic bacteria and plants are a promising anti-tumor and anti-HIV therapeutic (page 54, 1st paragraph).

The difference between the reference of Benning and the instant invention is that the reference of Benning does not teach a method of producing UDP-SQ from UDP-glucose with the polypeptide encoded by SEQ ID NO:6.

Essigmann et al. teach a polypeptide, plant SQD1, that catalyzes the formation of a UDP-sulfoquinovose from UDP-glucose and is orthologous to the SQDB (page 31, 4th paragraph and page 39). The SQD1 gene is 100% identical to SEQ ID NO:6 of the instant invention (GenEmbl database – Accession # AF022082). Essigmann et al. teach that said SQD1 gene and the bacterial sqdB gene (as mentioned above) are the only sufolipid genes known to be conserved between different organisms (page 31, 5th paragraph).

Essigmann et al. teach a method for transfecting a host cell with a DNA to express the encoded enzyme (page 32, 5th paragraph). Although Essigmann et al. states that the sulfur donor is unknown, Essigmann et al. teaches that a sulfite is a plausible sulfur donor (page 40, 3rd paragraph).

Transfecting a host cell with a desired gene is well known and practiced in the art (see Hall et al. – background) and multiple or sequential transformation is well known and practiced in the art. Many catalogs carry vectors and host cells capable of undergoing multiple transformations (pages 34-84 and appendix). Hall et al. teach host cells derived from dicotyledonous plants (see claims and Column 11) and Howard et al. teach host cells derived from monocotyledonous plants (Column 6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute the first reaction of SQDG synthesis of Benning with the SQD1 enzyme of Essigmann et al. The motivation of using the SQD1 is to provide a system in synthesizing SQDG using genes from a plant source and a bacterial source, thereby possibly increasing efficiency in production of SQDG. An efficient production of SQDG is attractive because sulfolipids are possible anti-tumor and anti-HIV therapeutics. One of ordinary skill in the art would have had a reasonable expectation of success since Benning outlines the pathway for SQDG production and production of a product using heterologous or orthologous enzymes are routinely performed in the art.

Response to Arguments

Applicant's arguments filed October 29, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

Claims 1, 13 and 15-16 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps in isolating the final product is still missing.

Claims 1, 13 and 15-16 remain rejected under 35 U.S.C. 103(a) as being obvious over Benning in view of Essigmann et al. and Guler et al.

Applicants argue that the identity of the sulfur donor was a mystery at the time the invention was filed and thereby the cited references do not teach the sulfur donor. The examiner disagrees. The cited references teach that a sulfur donor is need in the reaction. One of ordinary skill in the art would have had ample knowledge, skill and knowledge of type of sulfur donors.

Applicants refer to Yu et al. in aruguing that SQD1 and SQD2 have been co-expressed for the first time and thereby the new claims are patentable. The examiner disagrees. As discussed above, co-expression of multiple proteins via multiple vectors are well known and practiced in the art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

January 10, 2003

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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